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New Medicare Coverage Policy for Next-Generation Tumor Sequencing: A Key Shift in Coverage Criteria With Broad Implications Beyond Medicare

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The Centers for Medicare & Medicaid Services (CMS) recently issued a national coverage determination (NCD) on next generation tumor sequencing tests (NGTS) for patients with advanced cancer (see Box for definitions). The CMS policy provides coverage for NGTS tests that received a positive FDA review and that have FDA approved indications for patients with advanced solid cancers. NGTS tests must serve as companion diagnostics to target specific drug treatment(s). Labs that choose not to seek FDA review for their NGTS tests can seek local coverage determinations through CMS Medicare Administrative Contractors (MACs). Both the draft issuance on November 30, 2017 and the final policy issued on March 16, 2018 generated a great deal of controversy; over 300 comments were submitted to CMS during the public comment period on the draft issuance and numerous commentaries and news items have been published.

In this commentary, we argue that the new CMS policy (1) presents a key shift in coverage criteria for NGTS, and (2) has important implications beyond Medicare for private payer and Medicaid coverage policies. Our commentary draws on our prior and ongoing studies of coverage policies.(1–3) We also use insights from a meeting held on March 9, 2018, and accompanying survey conducted with our *UCSF Center for Translational and Policy Research on Personalized Medicine (TRANSPERS) Payer Advisory Board.* The Board includes senior executives from the largest private health plans, a Medicaid plan and leading

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regional private plans, as well as other thought leaders with expertise in coverage and reimbursement by Medicare and other payers.(4) We also build on our prior work that examined the broader health policy implications of the new CMS policy.(5, 6) Although observers have commented on the importance of the policy for private payers, there has been no assessment of the policy's implications for these payers and for Medicaid plans. Our previous work showed limited coverage of NGTS by private payers(7) and our more recent analyses of the largest private payers (unpublished data) confirmed that coverage of NGTS specifically is variable. Some payers cover NGTS only for specific cancer sites (e.g., non-small cell lung cancer) and others cover only panels with a limited number of genes (e.g., less than 50). For state Medicaid plans, we are unaware of any published analyses of NGTS coverage policies, but coverage has been described as limited and variable.(8)

(1) Why the CMS Policy Represents a Key Shift in Coverage Criteria

The new CMS policy represents a departure from Medicare's previous criteria as well as from criteria currently used for NGTS coverage by private payers and Medicaid plans in several ways (Table 1).

Notably, there are criteria that some private payers use that were not included in the CMS policy, e.g., that sequential single-gene testing is found to be impractical for a patient before they will cover a panel. As another example, some private payer policies refer to guidelines such as those by the National Comprehensive Cancer Network (NCCN) and this criterion was not mentioned in the CMS policy.

One feature of the CMS policy included in the draft but not in the final version would have represented another key shift in the criteria used: the proposed pathway for tests not meeting the coverage criteria to still be covered via Medicare's "coverage with evidence development" program if laboratories collected the required data. This approach had been recommended by some observers(9) but generated intense debate. Our discussions with private and Medicaid payers suggest that they perceived that the adoption and implementation of CED would be very difficult.

(2) Implications for Private Payers and Medicaid Plans

We argue that there are three key implications for private payers and Medicaid plans:

1. Private payers and Medicaid plans will carefully review the CMS policy and monitor its implementation, but they may not change their own coverage policies to match those of CMS in the short-term.

Our previous research and recent payer input show that CMS policy is a factor in their considerations, e.g., in our meeting, payers noted they perceive this policy as important. However, contrary to a common assumption, private payers and Medicaid do not always follow Medicare policies as Medicare decisions are only one of many factors that they consider. For example, a review of 47 Medicare NCDs for medical devices found that Medicare policies were equivalent to the corresponding private payer policies only about

half the time.(10) Medicaid policies are different for each state and thus can be even more variable.

In our discussions with payers, we found that many of them are unsure of their plans or do not plan to change their policies to match the CMS policy at least in the short term. Payers stated that the new CMS policy provides some benefits and a step forward but they also perceived that it creates concerns that have to be addressed because of the significant shift in the criteria used as described above. They planned to make their own assessments for coverage; as one payer noted, to the extent that conclusions drawn by CMS are well supported by analysis of literature and other factors, they would draw the same conclusion without the CMS policy.

2. Private payers and Medicaid plans that decide to change their coverage policies to match those of CMS will need to make adaptations.

One key difference in the situation faced by private payers versus the CMS is that private payers do not have the option of the second coverage pathway that is included in the CMS policy – the use of Medicare Administrative Contractors to make local coverage decisions for tests not already covered by the national policy. The Medicare program thus has the flexibility to adapt policies to local situations, whereas private payers typically do not have the flexibility to have differing policies at the national and local levels. Thus, for example, even though an FDA positive review is required by the Medicare national coverage policy the Medicare local policies may not require this level of review, while private payers will have to either require FDA positive review or not require it.

Changes in coverage policies are also likely to have ripple effects on the laboratory and medical center industries that will require adaptation by private payers and Medicaid plans. Many NGTS tests are developed and conducted at specific laboratories for use at their own facilities, such as medical center-based tests. These tests are often not submitted to the FDA for approval, unlike the tests developed by large, commercial laboratories. It is possible that the CMS national coverage policy requirement for a positive FDA review will encourage smaller laboratories to submit their tests for approval and thus increase the number of approved tests. However, FDA review can be time-consuming and expensive and thus we believe that most smaller laboratories will not pursue this option. The result may be that private payers and Medicaid plans have fewer testing options for their patients.

The criteria used in the CMS policy will also require refining definitions such how “advanced cancer” is measured, e.g., by incorporating the evolving concept of tumor mutational burden (TMB) in solid tumors. Of particular importance will be whether there are billing codes (i.e., CPT codes) that capture the needed information and that are consistently adopted and implemented. Payers need to be able to track what tests are being ordered and reimbursed in order to support their policies. However, we recently found that there remain large gaps in the codes used for multigene tests as a category and wide variation in whether and how they are implemented.(11)

We also found that some payers are considering or implementing other approaches to deal with coverage issues for NGTS that differ from the approach used by CMS. For example,

some payers are providing broader coverage but doing so while also implementing utilization management programs (e.g., pre-authorization requirements, contracting agreements, and/or use of lab benefit managers). Each payer has a different enrollee population and faces different financial and logistical situations such that one approach may not work for all payers.

3. In the medium to long-term, we expect to see an evolution of coverage such that at least some private payers and Medicaid plans will establish positive coverage policies for NGTS in at least some clinical situations

By viewing the past development of NGTS policies, we see that they have evolved over time and the CMS policy emerged from the gaps in that evolution.(3) A number of experts have called for adaptation of coverage frameworks for next-generation sequencing tests(1, 2, 12) and several frameworks have been proposed.(12–14) These approaches all have pros and cons, and their acceptance and implementation have varied.(3) Regardless, it is clear that the lack of positive coverage policies for NGTS (where payers agree to pay for the test provided criteria are met) for NGTS was a gap and CMS determined that they needed to address that gap.

We can speculate that private payer coverage will evolve over time with at least some policies that provide broad coverage for NGTS. Private plans servicing Medicare Advantage plans have a mandate to cover NGTS for those enrollees – a dichotomy in their own policy that may move them toward consistent coverage for all enrollees. Also, the CMS policy will likely increase demand for NGTS by providers and patients that will create greater impetus for payers to cover it. In contrast, there is more uncertainty about what Medicaid plans will cover given the current political environment and financial pressures.

In sum, the CMS policy represents a key shift in NGTS coverage criteria with implications far beyond this specific policy. It will be important to track and assess how other payers respond and the impact of policies on patients and providers. We suggest that mechanisms be developed so that all relevant stakeholders can participate in an assessment of the implementation and implications of this new policy including the benefits and the risks.

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Glossary

National Coverage Determination (NCD)
Nationwide determination of whether Medicare will pay for an item or service. In the absence of an NCD, a service is covered at the discretion of regional Medicare Administrative Contractors who may issue a Local Coverage Determination (LCD)

Medicare Administrative Contractors (MACs)
A private health care insurer that has been awarded a geographic jurisdiction to process Medicare claims

Next generation tumor sequencing (NGTS

The use of massively parallel technologies to simultaneously examine large numbers of genetic tumor alterations

Companion diagnostics

A test that uses genetic information to inform a decision to use a specific drug treatment

FDA positive review

Tests can receive a positive review from the FDA via the “approval” process or if they are “cleared” through a determination that they are substantially equivalent to a test already approved

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Table 1:

Criteria Used In CMS NCD and How They Represent Key Shifts Compared To Previous CMS and Current Private Payer / Medicaid Criteria

Coverage Criteria Used in CMS NCD	**How CMS NCD Criteria Differs from Current Criteria Used by Private Payers and Medicaid Plans**
FDA positive review required for test	Typically, not required
Test must be a companion diagnostic	Typically, not required
No limit on the number of included genes in an NGTS panel	Many previous coverage policies and coverage frameworks called for limiting coverage of NGTS tests based on a specific number of genes, e.g., a proposal by the Center for Medical Technology Green-Park Collaborative used 50 genes as a cut-off.(8)
Inclusion of less-studied genes does not define the entire test as experimental/investigational and thus not covered	If any included gene was experimental/investigational, this typically made the test not coverable.
NGTS tests meeting other policy criteria are covered for any advanced solid tumors	Typically, cancer-specific, e.g. non-small cell lung cancer.
Policy focuses on a test *method* (sequencing) versus the *testing clinical scenario* irrespective of what method is being used	Policies more commonly focus on the clinical scenario rather than the test method.